No. 14-15624

IN THE UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

PLANNED PARENTHOOD OF ARIZONA, INC; WILLIAM RICHARDSON, M.D., and WILLIAM H. RICHARDSON M.D. P.C., doing business as Tucson Women's Center,

Plaintiffs-Appellants,

v.

WILLIAM HUMBLE, Director of the Arizona Department of Health Services, in his official capacity,

Defendant-Appellee.

On Appeal from the United States District Court for the District of Arizona
Civil Action No. 4:14-cv-01910-TUC-DCB

BRIEF OF AMICI CURIAE AMERICAN COLLEGE OF OBSTETRICIANS AND GYNECOLOGISTS AND THE AMERICAN MEDICAL ASSOCIATION IN SUPPORT OF PLAINTIFFS-APPELLANTS AND IN SUPPORT OF REVERSAL

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STATEMENT OF INTEREST OF AMICI CURIAE

The American College of Obstetricians and Gynecologists (the "College" or "ACOG") and the American Medical Association ("AMA") submit this brief amici curiae in support of Appellants.[1]

ACOG is a non-profit educational and professional organization founded in 1951. The College's objectives are to foster improvements in all aspects of healthcare of women; to establish and maintain the highest possible standards for education; to publish evidence-based practice guidelines; to promote high ethical standards; and to encourage contributions to medical and scientific literature. The College's companion organization, the American Congress of Obstetricians and Gynecologists (the "Congress"), is a professional organization dedicated to the advancement of women's health and the professional interests of its members.

Sharing more than 57,000 members, including 946 in Arizona, the College and the Congress are the leading professional associations of physicians who specialize in the healthcare of women.

[1] Pursuant to Federal Rule of Appellate Procedure 29, the parties have consented to the filing of this amicus brief. Also pursuant to Rule 29, undersigned counsel for amici curiae certify that: (1) no counsel for a party authored this brief in whole or in part; (2) no party or party's counsel contributed money that was intended to fund the preparation or submission of this brief; and (3) no person or entity—other than amici curiae, its members, and its counsel—contributed money intended to fund the preparation or submission of this brief.

The College and the Congress recognize that abortion is an essential health care service and oppose laws regulating medical care that are unsupported by scientific evidence and that are not necessary to achieve an important public health objective.

The College has previously been granted leave to appear as amicus curiae in various courts throughout the country, including the U.S. Supreme Court. In addition, the College's work has been cited frequently by the Supreme Court and other federal courts seeking authoritative medical data regarding childbirth, abortion, and other aspects of healthcare for women.[2]

AMA is the largest professional association of physicians, residents and medical students in the United States. Additionally, through state and specialty medical societies and other physician groups, seated in the AMA's House of

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[2] *See, e.g.*, *Stenberg v. Carhart*, 530 U.S. 914, 932-936 (2000) (quoting ACOG's amicus brief extensively and referring to ACOG as among the "significant medical authority" supporting the comparative safety of the abortion procedure at issue); *Hodgson v. Minnesota*, 497 U.S. 417, 454 n.38 (1990) (citing ACOG's amicus brief in assessing disputed parental notification requirement); *Simopoulos v. Virginia*, 462 U.S. 506, 517 (1983) (citing ACOG publication in discussing "accepted medical standards" for the provision of obstetric-gynecologic services, including abortions); *Planned Parenthood of Wis., Inc. v. Van Hollen*, 738 F.3d 786, 790 (7th Cir. 2013) (citing studies discussed in an ACOG amicus brief); *see also Gonzales v. Carhart*, 550 U.S. 124, 170-171, 175-178, 180 (2007) (Ginsburg, J., dissenting) (referring to ACOG as "experts" and repeatedly citing ACOG's amicus brief and congressional submissions regarding abortion procedure); *Greenville Women's Clinic v. Bryant*, 222 F.3d 157, 168 (4th Cir. 2000) (extensively discussing ACOG's guidelines and describing those guidelines as "'commonly used and relied upon by obstetricians and gynecologists nationwide to determine the standard and the appropriate level of care for their patients'").

Delegates, substantially all U.S. physicians, residents, and medical students are represented in the AMA's policy-making process. The objectives of the AMA are to promote the science and art of medicine and the betterment of public health. AMA members practice in all fields of medical specialization and in every state, including Arizona.

SUMMARY OF ARGUMENT

The district court correctly recognized that medical abortion is extremely safe; that the medical abortion regimens employed by Plaintiffs-Appellants ("Appellants") constitute sound medical practice in line with medical norms and the best interests of patients; and that there is no evidence that A.R.S. § 36-449.03(E)(6) and its implementing regulation (A.A.C. R9-10-1508(G)) (collectively the "the Arizona law") promote women's health.[3] There is no

[3] Amici do not in this brief repeat arguments regarding the infirmities of the district court's legal reasoning, as such arguments are set forth in full in Appellants' brief. *See* Circuit Advisory Committee Note to Rule 29-1 (noting that "the Court will review the amicus curiae brief in conjunction with the briefs submitted by the parties," and cautioning "that amici briefs should not repeat arguments or factual statements made by the parties"). Moreover, and unless expressly discussed herein, amici do not express an opinion on all or other aspects of A.R.S. § 36-449.03 or A.A.C. R9-10-1508. In particular, amici do not express an opinion whether the Arizona law effectively outlaws all medical abortion or whether it restricts medical abortion to the regimen set forth on the Food and Drug Administration-approved label for mifepristone. As discussed more fully herein, either interpretation poses serious risks to public health by, *inter alia*, limiting the availability of a safer and more effective medical procedure and undermining the sound judgment of medical practitioners.

question that the Arizona law confers significant risk and no benefit to women's health. Put simply, the law is bad medicine.

The Arizona law jeopardizes women's health by requiring that physicians deny women the benefit of the most current, well-researched, safe, evidence-based, and proven protocols for the provision of medical abortion and, instead, prescribe a regimen that is outdated and less safe. By imposing a regimen that does not serve the best interests of patients, the law also requires that physicians depart from their ethical obligation to provide the best possible care for their patients using their sound medical judgment—insisting, rather, that physicians substitute the judgment of the Arizona legislature for their own. There is no medical basis to limit a physician's discretion to administer the most up-to-date, evidence-based regimen and to relegate Arizona women to an outdated, less safe, and less effective protocol. Such a restriction deprives women of the best available medical care, stifles medical advancement, and serves no legitimate purpose.

For these and the reasons set forth below, amici, the leading medical societies whose policies represent the considered judgments of the vast majority of physicians in this country, urge this Court to reverse the district court's ruling, preserve the injunction already in place, and remand for further proceedings.

I. THE ARIZONA LAW CONFERS NO MEDICAL BENEFIT AND DEPARTS FROM COMMONLY ACCEPTED MEDICAL PRACTICES

The Arizona law binds physicians who administer medical abortions to an inferior protocol identified on the drug label for mifepristone approved by the Food and Drug Administration ("FDA") more than thirteen years ago. The current state of medical knowledge—including knowledge regarding the various benefits associated with evidence-based medical abortion regimens and the existence of health conditions where medical abortion is preferred over surgical abortion—makes clear why this Court should reverse the district court and preserve the current injunction.

A. The Arizona Law Binds Physicians To An Outdated And Less Effective Protocol

The practice of medicine should be based on the latest scientific research and medical advances. Where, as here, there is no substantial public health justification,[4] indeed no health justification whatsoever, legislatures should not interfere with patient care, the exercise of physicians' sound medical judgment, or the patient-physician relationship.[5] Laws mandating treatment protocols that are

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[4] *See* District Court March 31, 2014 Order at 7 (Excerpts of Record ("ER") 07) (conceding that "[t]here is no evidence before the Court regarding any supporting evidence for any asserted legislative fact" with respect to risk or negative outcome for medical abortion).

[5] ACOG, Statement of Policy, *Legislative Interference with Patient Care, Medical Decisions, and the Patient-Physician Relationship* (May 2013), *available at* http://www.acog.org/~/media/Statements%20of%20Policy/Public/2013 LegislativeInterference.pdf ("ACOG Statement of Policy on Legislative Interference"); *see also* AMA, Policy H-120.988, *Patient Access to Treatments Prescribed by Their Physicians*, *available at* https://download.ama-assn.org/

contrary to best medical practice guidelines are dangerous to patient health.[6] Even laws that mandate a protocol that is valid at the time of the particular law's enactment are ill-advised because medical knowledge is not static and continues to advance in the time after a law's passage.[7] As knowledge advances, medical treatments enshrined within such laws become outdated, denying patients the best evidence-based care and depriving physicians of the ability to use their medical judgment to serve the interests of their patients.[8]

Medical knowledge and experience call for the use of regimens for the provision of medical abortion that, for many years, have surpassed the regimen for medical abortion described on the FDA-approved label for mifepristone. In 2000, the FDA approved final labeling for mifepristone, used together with another medication called misoprostol, for use in ending early pregnancy. Since that time, and as a result of continued medical research—including research building on more than three decades of studies of various medical abortion regimens—a number of evidence-based regimens have emerged that make medical abortion safer, faster, and less expensive, and that result in fewer complications as

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resources/doc/PolicyFinder/policyfiles/HnE/H-120.988.HTM (affirming the AMA's strong "support for the autonomous clinical decision-making authority of a physician").

6 ACOG Statement of Policy on Legislative Interference.

7 *Id.*

8 *Id.*

compared to the protocol set forth on the label approved by the FDA more than thirteen years ago.

In March 2014, ACOG issued its Practice Bulletin Number 143 on the Medical Management of First-Trimester Abortion ("Practice Bulletin No. 143").[9] The conclusions in Practice Bulletin No. 143 are premised on recent studies that have shown the superiority of evidence-based regimens[10] as compared to the

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[9] ACOG, Practice Bulletin No. 143, *Medical Management of First-Trimester Abortion* (Mar. 2014). ACOG's guidelines are designed to aid practitioners in making decisions about appropriate patient care, but do not dictate an exclusive course of treatment or procedure. *See id*. at 1. *See generally*, ACOG, *Reading the Medical Literature*, *available at* http://www.acog.org/Resources_And_Publications/Department_Publications/Reading_the_Medical_Literature (describing in detail ACOG's methodical and comprehensive guideline development process).

Practice Bulletin No. 143 replaced ACOG Practice Bulletin Number 67, Medical Management of Abortions, which was issued in October 2005, and concluded, among other things, that then-available good and consistent scientific evidence demonstrated that, as compared with the regimen described on the FDA-approved label, regimens using 200 mg of mifepristone orally and 800 µg of misoprostol vaginally were associated with better outcomes, fewer side effects, and lower cost for women with pregnancies up to 63 days of gestation. ACOG, Practice Bulletin No. 67, *Medical Management of Abortion*, 8 (Oct. 2005). Thus, the state of scientific research and evidence, as of at least 2005, supported the use of certain alternative regimens over the regimen described on the FDA-approved label, which had been approved several years earlier.

[10] "Evidence-based" describes uses or regimens that are based on scientific evidence but may be "off-label"—in other words, that may depart from the regimen included on the Final Printed Labeling for a particular drug as approved by the FDA. *See infra* pp. 13-15.

thirteen-year-old regimen set forth on the FDA-approved label.[11] For example, Practice Bulletin No. 143 concluded, among other things, that "[b]ased on efficacy and adverse effect profile, evidence-based protocols for medical abortion are superior to the FDA-approved regimen. Vaginal, buccal, and sublingual routes of misoprostol administration increase efficacy, decrease continuing pregnancy rates, and increase the gestational age range for use as compared with the FDA-approved regimen."[12] Practice Bulletin No. 143 also concluded that lower doses of mifepristone (200 mg) have similar efficacy and lower costs compared to those regimens that use mifepristone at 600 mg.[13] Practice Bulletin No. 143, moreover, determined that women can "safely and effectively self-administer misoprostol at home as part of a medical abortion regimen," eliminating the need for women to return to a health care facility for the administration of misoprostol as outlined on the FDA-approved label.[14]

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11 *See, e.g.*, Cleland et al., *Signficant Adverse Events and Outcomes After Medical Abortion*, 121 Obstetrics & Gynecology 166 (Jan. 2013); Schaff, *Mifepristone: Ten Years Later*, 81 Contraception 1, 1-7 (Jan. 2010); Ngo et al., *Comparative Effectiveness, Safety and Acceptability of Medical Abortion at Home and in a Clinic: A Systematic Review*, 89 Bull. World Health Org. 360 (May 2011) (concluding that home-based self-administration of misoprostol as part of mifepristone-misoprostol medical abortion was safe and effective under the conditions in place in the included studies).

12 Practice Bulletin No. 143 at 11.

13 *Id.*

14 *Id.*

In addition to these conclusions, data also indicate that the overall risk of serious infection with medical abortion is very low and that buccal administration of misoprostol may result in a lower risk of serious infection compared with vaginal administration.[15] In fact, evidence-based regimens through at least 63 days of gestation are safer and more effective than the regimen described on the FDA-approved label when used up to 49 days of gestation.[16] As with any medical care, treatments that are safer and more effective are medically preferable.

B. The Arizona Law Lacks A Public Health Justification And Threatens Women's Health

The Arizona law's restriction on the regimens that can be used for medical abortion is harmful to women and lacks any public health justification.

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[15] Cleland et al., 121 Obstetrics & Gynecology at 166-171; Mary Fjerstad et al., *Rates of Serious Infection after Changes in Regimens for Medical Abortion*, 361 N. Eng. J Med. 145, 145-51 (2009).

[16] After 49 days of gestation, the efficacy of the regimen described on the FDA-approved label declines significantly, and the likelihood of continuing pregnancy increases. Creinin & Spitz, *Use of Various Ultrasonographic Criteria to Evaluate the Efficacy of Mifepristone and Misoprostol for Medical Abortion*, 181 Am. J. Obstetrics & Gynecology 1419, 1419-1424 (1999). However, regimens using vaginal, sublingual and buccal misoprostol provide efficacy rates up to 63 days of gestation that exceed the approximately 92% efficacy of the regimen described on the FDA-approved label up to 49 days of gestation. Spitz et al., *Early Pregnancy Termination with Mifepristone and Misoprostol in the United States*, 338 N. Eng. J. Med. 1241, 1241-1247 (1998); Regina Kulier et al., *Medical Methods for First Trimester Abortion (Review)*, Cochrane Collaboration (John Wiley & Sons, Ltd. ed. 2011); Schaff, 81 Contraception at 1-7; Cleland et al., 121 Obstetrics & Gynecology at 166-171.

As noted, the Arizona law binds physicians to using a regimen that is outdated and is less medically beneficial to women. But, the law's restriction on the regimens that can be used for medical abortion is especially harmful to those women with certain medical conditions that make first-trimester medical abortion (even after 49 gestational days) recommended over other abortion methods, such as aspiration. Those conditions include certain uterine anomalies and a stenotic (narrow) cervix.[17] Prior to 2000 when mifepristone was approved by the FDA, medical abortion regimens not including mifepristone were recommended in lieu of aspiration or other instrumental methods for patients with the medical conditions described above.[18] The Arizona law imposes a new prohibition on the use of non-mifepristone regimens because those regimens, too, are prescribed off-label. As a result, under the Arizona law, women with gestation exceeding 49 days and who have medical conditions contraindicative to surgical abortion will be unable to

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[17] Schaff et al., *Methotrexate and Misoprostol When Surgical Abortion Fails*, 87 Obstetrics & Gynecology 450, 450-452 (1996); Creinin, *Medically Induced Abortion in a Woman With a Large Myomatous Uterus*, 175 Am. J. Obstetrics & Gynecology 1379, 1379-1380 (1996).

[18] *See* Schaff, 87 Obstetrics & Gynecology at 450-452; Creinin, 175 Am. J. Obstetrics & Gynecology at 1379-1380. Methotrexate is FDA-approved for treatment of certain cancers, psoriasis, and rheumatoid arthritis. *See* Methotrexate Injection, FDA label, *available at* http://www.accessdata.fda.gov/drugsatfda_docs/label/2011/011719s117lbl.pdf. Misoprostol is FDA-approved for use relating to gastric ulcers. *See* Cytotec (misoprostol), FDA label, *available at* http://www.accessdata.fda.gov/drugsatfda_docs/label/2002/19268slr037.pdf.

obtain a medical abortion despite strong medical need, leaving them worse off than they would have been before 2000. Such a regression is clearly harmful to women's health.

Nor does the law have any public health justification. Contrary to the Arizona legislature's suggestions otherwise, good and consistent scientific research shows the evidence-based regimens are low risk and supports the use of evidence-based protocols over the regimen described on the FDA-approved label.[19] Indeed, while concerns about serious, rare, and deadly infection with clostridial bacteria in women having medical abortion have been raised by the Arizona legislature,

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[19] That there have been eight infection-related deaths reported to the FDA that involved the vaginal and buccal administration of misoprostol versus no infection-related deaths reported to the FDA that involved the regimen described on the FDA-approved label is of no import because the regimen set forth on the label approved by the FDA has been disfavored and not widely used for many years. *See* FDA, *Mifepristone U.S. Postmarketing Adverse Events Summary through 04/30/2011*, *available at* http://www.fda.gov/downloads/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/UCM263353.pdf (summarizing reported adverse events); Wiegerinck et al., *Medical Abortion Practices: A Survey of National Abortion Federation Members in the United States*, 78 Contraception 486, 88 (2008) (finding that in 2001 "[t]he combination of 200 mg mifepristone followed by home use of 800 mcg vaginally administered misoprostol, commonly referred to as the alternative or evidence-based regimen, was used by 83% of facilities. The FDA-approved regimen…was used in only 4% of facilities."). According to the aforementioned FDA adverse report data, through April 2011, approximately 1.52 million women used mifepristone in the U.S., resulting in a fatality rate due to infection of 0.0005 percent, which is extremely low. Given the infrequent use of the regimen described on the FDA-approved label, one would not expect to see any deaths associated with the small set of women that have received medical abortion that followed the regimen set forth on the FDA-approved label.

research shows no specific connection between clostridial organisms and medical abortion.[20] Furthermore, it is now recognized that clostridial species are, for reasons having nothing to do with abortion, a more common cause of pelvic infection generally than previously believed.[21] Thus, any purported justification for the law based on an alleged connection between medical abortion and clostridial organisms is medically unsound.

To be sure, all medications carry risk, but the risks associated with evidence-based use of mifepristone and misoprostol are comparably low.[22] Indeed, many drugs that are used in ways other than those specified on the FDA's approved label pose equal or greater risk to patients than Appellants' evidence-based use of mifepristone and misoprostol to induce abortions. For example, the drug Neurontin is approved for only a few indications, including epilepsy. Nonetheless, despite its serious side effects, which "include suicidal behavior and ideation, tumor potential, and viral and respiratory infections," Neurontin is commonly

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[20] Practice Bulletin No. 143 at 8. Investigators have found these organisms also are associated with other obstetric and gynecological procedures, including miscarriage (spontaneous abortion), term delivery, surgical abortion, and medical procedures for cervical dysplasia. *See* Cohen et al., *Toxic Shock Associated with Clostridium sordellii and Clostridium perfringens After Medical and Spontaneous Abortion*, 110 (5) Obstetrics & Gynecology 1027 (2007); Ho et al., *Undiagnosed Cases of Fatal Clostridium-Associated Toxic Shock in Californian Women of Childbearing Age*, 201 Am. J. Obstetrics & Gynecology 459 (Nov. 2009).

[21] Practice Bulletin No. 143 at 8.

[22] *See supra* pp. 6-9.

prescribed off-label for diabetic neuropathy and chronic pain.[23] Wellbutrin is another example; approved by the FDA as an anti-depressant, it is often used for smoking cessation.[24] Wellbutrin's side effects include, among others: suicidal behavior and ideation, seizure, and hypertension. In fact, the complications associated with mifepristone and misoprostol are far less serious than those associated with other medications that are routinely used off-label, further undermining the State's claim of any public health benefit that would justify the Arizona law. Thus, the State's claimed justification for the law is belied not only by the science, *see supra* at 6-9, but also by the commonplace and often necessary practice of prescribing comparatively riskier medications off-label.

II. BY MANDATING COMPLIANCE WITH THE REGIMEN DESCRIBED ON THE MIFEPRISTONE LABEL, THE ARIZONA LAW IS INCONSISTENT WITH COMMON MEDICAL PRACTICE AND PROHIBITS PHYSICIANS FROM ACTING IN THE BEST INTEREST OF THEIR PATIENTS

More fundamentally, the Arizona law's reliance on the "protocol that is authorized by the [FDA] and that is outlined in the final printing labeling instructions" is based on a complete misunderstanding of the role of the FDA in approving medications. While the State bases its position on "the FDA-approved

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[23] Declaration of Lisa D. Rarick, M.D. ("Rarick Decl.") ¶ 20 (ER 85).

[24] Declaration of Daniel Grossman, M.D. ("Grossman Decl.") ¶ 30 (ER 54).

protocol,"[25] that protocol is merely derived from the Final Printed Labeling ("FPL") approved in 2000 for mifepristone. An FPL is an informational document that is meant to provide physicians with guidance about how to use a drug.[26] However, because a drug manufacturer need only demonstrate the safety and efficacy of a drug for a particular use in order to earn initial FDA approval of the medication for marketing, economic considerations often constrain manufacturers from seeking FDA approval for additional uses.[27] The FDA requires a drug manufacturer to update the FPL with new information about a drug's safety, but it does not require updates for new uses or protocols developed for that drug.[28] Nor does the FPL impose binding obligations on physicians or restrict the medical profession's ability to develop new uses for the approved drug.[29] Accordingly, that the FDA has approved a drug based on a particular regimen does not imply that the

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[25] *See, e.g.*, Appellee's Response to Appellants' Emergency Motion Under Circuit Rule 27-3 For an Injunction Pending Appeal (Apr. 4, 2014), Dkt. 11-1, at 1, 3, 12.

[26] Rarick Decl. ¶ 11 (ER 82).

[27] FDA Drug Bulletin, Vol. 12, No. 1, *Use of Approved Drugs for Unlabeled Indications*, 5 (Apr. 1982) ("FDA Drug Bulletin") (noting that "without the initiative of the drug manufacturer whose product is involved" new use regimens may never be added to approved drug labeling); Grossman Decl. ¶ 31 (ER 54).

[28] Rarick Decl. ¶ 12 (ER 82).

[29] FDA Drug Bulletin at 5.

regimen is the safest or best use for the drug. Indeed, the FDA itself has observed that "[t]he term 'unapproved uses' is, to some extent, misleading."[30]

Although the FDA has regulatory authority over the manufacturers of drugs and medical devices, it does not—and cannot—regulate physicians and the practice of medicine.[31] It is common for medical practice to advance beyond what is described on FDA drug labels. The FDA allows "off-label" use of registered products—meaning use that is not expressly provided for in an FDA-approved FPL—when existing medical evidence supports such use.[32] "Up to 20% of all drugs are prescribed off-label and among some classes of cardiac drugs, off-label use can be as high as 46%."[33] Off-label use is common, even predominant, in the treatment of cancer patients.[34] The FDA has, itself, noted that "[g]ood medical practice and the best interests of the patient *require* that physicians use legally

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30 FDA Drug Bulletin at 5.

31 *Id.* at 4-5; Rarick Decl. ¶ 11 (ER 82).

32 FDA Drug Bulletin at 4-5 (off-label use "may be appropriate and rational in certain circumstances, and may, in fact, reflect approaches to drug therapy that have been extensively reported in medical literature").

33 AMA National Task Force on CME Provider/Industry Collaboration Fact Sheet, Vol. 2, Issue 3, *On-Label and Off-Label Usage of Prescription Medicines and Devices, and the Relationship to CME*, *available at* https://cme.wustl.edu/forms/On_Label_and_Off_Label_Usage_of_Prescription_Medicines_and_Devices_and_the_Relationship_to_CME.pdf.

34 *See* United States General Accounting Office, Report to the Chairman, Committee on Labor and Human Resources, U.S. Senate, *Off-Label Drugs: Reimbursement Policies Constrain Physicians in Their Choice of Cancer Therapies* (Sept. 1991), *available at* http://archive.gao.gov/d18t9/144933.pdf.

available drugs, biologics and devices according to their best knowledge and judgement."[35]

Indeed, medical ethical standards dictate that medical professionals provide the best possible care for their patients. For example, AMA policy provides that "[w]ithin the patient-physician relationship, a physician is ethically required to use sound medical judgment, holding the best interests of the patient as paramount."[36] Similarly, ACOG's Code of Professional Ethics states that "the welfare of the patient must form the basis for all medical judgments. … The obstetrician-gynecologist should … exercise all reasonable means to ensure that the most appropriate care is provided to the patient."[37] It is therefore unsurprising that off-label use of drug products is also supported by the medical community.[38] AMA

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[35] FDA Information Sheet, *"Off-Label" and Investigational Use Of Marketed Drugs, Biologics, and Medical Devices*, *available at* http://www.fda.gov/regulatoryinformation/guidances/ucm126486.htm (emphasis added).

[36] AMA, Opinion 10.015, *The Patient-Physician Relationship*, *available at* http://www.ama-assn.org/ama/pub/physician-resources/medical-ethics/code-medical-ethics/opinion10015.page?.

[37] ACOG, Code of Professional Ethics of the American College of Obstetricians and Gynecologists, *available at* http://www.acog.org/~/media/Departments/National%20Officer%20Nominations%20Process/ACOGcode.pdf.

[38] *See, e.g.*, AMA, Policy H-120.988, *Patient Access to Treatments Prescribed by Their Physicians*, *available at* https://download.ama-assn.org/resources/doc/PolicyFinder/policyfiles/HnE/H-120.988.HTM (confirming the AMA's strong support for the proposition that "a physician may lawfully use an FDA approved drug product or medical device for an unlabeled indication when such use is based upon sound scientific evidence and sound medical opinion").

policy, for example, provides that "[t]he official labeling should not be regarded as a legal standard of acceptable or accepted medical practice nor as a substitute for clinical judgment or experience nor as a limitation on usage of the drug in medical practice."[39] But the Arizona law does just that. By requiring a physician to administer medical abortion only in the way that happened to have been set forth on the FPL for mifepristone more than thirteen years ago, the Arizona law impedes physician discretion and contravenes medical ethics by outlawing the safest, most effective method of medical abortion and relegating women to an outdated, inferior treatment.

CONCLUSION

For the reasons stated above, amici urge the Court to reverse the district court's ruling, preserve the current injunction, and remand for further proceedings.

[39] AMA, Policy H-115.994, *Prescription Product Labeling*, *available at* https://download.ama-assn.org/resources/doc/PolicyFinder/policyfiles/HnE/H-115.994.HTM.

April 23, 2014

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

1. This brief complies with the type-volume limitation of Federal Rule of Appellate Procedure 32(a)(7)(B) because this brief contains 4,211 words, excluding the parts of the brief exempted by Federal Rule of Appellate Procedure 32(a)(7)(B)(iii).

2. This brief complies with the typeface requirements of Federal Rule of Appellate Procedure 32(a)(5) and the type style requirements of Federal Rule of Appellate Procedure 32(a)(6) because this brief has been prepared in a proportionally spaced typeface using Microsoft Word 2010 in 14-point font size and Times New Roman type style.

/s/ Kimberly A. Parker

Counsel for Amici Curiae

CERTIFICATE OF SERVICE

I hereby certify that, on April 23, 2014, I electronically filed the foregoing Brief of Amici Curiae American College of Obstetricians and Gynecologists and the American Medical Association in Support of Plaintiffs-Appellants and In Support of Reversal with the Clerk of Court by using the CM/ECF system, which will send a notice of electronic filing to counsel for the parties .

/s/ Kimberly A. Parker

Counsel for Amici Curiae